(19) Japan Patent Office (JP)

(11) Japanese Unexamined Patent Application Publication

(12) **Japanese Unexamined Patent Application Publication** (A)

S59-39834

(51) Int. Cl.³	Identification codes	JPO file numbers
A 61 K 47/00		7057-4C
// A 61 K 9/48		7057-4C

(43) Publication date March 5, 1984

Number of inventions 1
Request for examination Not yet requested

(Total of 2 pages)

(54) FILM COMPOSITION FOR PREPARATION

(21) Japanese Patent Application S57-152080
(22) Date of Application August 31, 1982

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SPECIFICATION

1. TITLE OF THE INVENTION

Film composition for preparation

2. SCOPE OF PATENT CLAIMS

1. Film composition for preparation containing 0.1–10 parts by weight citric acid per 100 parts by weight gelatin.

2. Film composition set forth in Claim 1 wherein the gelatin is dual-treated.

3. DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a film composition for preparation, particularly to a film composition for readily soluble preparation.

Prior to now, in the most commonly used preparations of vitamins, oily components, etc., particularly readily soluble preparations, the content was coated with a gelatin-based film, which was a problem because the film was generally not sufficiently soluble and furthermore its solubility deteriorated over time (slowing the disintegration time).

One method that has been proposed to solve these problems is to add organic acid such as tartaric acid or fumaric acid to gelatin. However, although this method improves the solubility of the film, it does not prevent the slowing of disintegration time over time.

As a result of assiduous research conducted in view of this situation, the inventors completed the present invention by discovering that adding citric acid to the gelatin serving as the film base makes it possible to overcome these disadvantages pertaining to solubility without reducing the producibility of the preparation.

In short, the present invention relates to a film composition for preparation containing 0.1–10 parts by weight ~~anhydrous~~ citric acid per 100 parts by weight gelatin.

Examples of gelatin that can be used in the present invention include acid-treated gelatin and alkali-treated gelatin, which have for a long time been commonly used in film compositions for readily soluble preparations, as well as dual-treated gelatin treated by acid treatment first and then by alkali treatment, but dual-treated gelatin is particularly preferable.

Acid-treated gelatin generally functions better to prevent the slowing of disintegration time, but does not have as good producibility as alkali-treated gelatin, whereas conversely, alkali-treated gelatin has good producibility, but tends to be inferior to acid-treated gelatin in terms of preventing the slowing of disintegration time.

In contrast, dual-treated gelatin has a high jelly strength (normally 200–300 bloom), and a relatively low viscosity, which makes it superior in terms of both producibility and ability to prevent the slowing of disintegration time.

The proportion in which to mix the gelatin and citric acid is normally 0.1–10 parts by weight of the latter to 100 parts by weight of the former, as adding less than 0.1 parts by weight citric acid will make it difficult to obtain the effect of the invention, and adding more than 10 parts by weight will make it difficult to form a preparation.

The readily soluble preparation in the present invention is made by suitably mixing the aforesaid gelatin and citric acid together with conventional compounding ingredients such as D-sorbit, purified water, glycerin, preservative, etc.

By coating some suitable content such as vitamin E, vitamin A or cod-liver oil using the film composition prepared, as per the aforesaid mixing formulation, according to the conventional method, a readily soluble preparation with a film that is sufficiently soluble and is able to prevent deterioration of solubility over time can be manufactured with good production efficiency.

Although the film in the present invention can be used generally on any readily soluble preparation, it is particularly suited to coating soft capsules.

Embodiments of the present invention will be described below.

Embodiments 1–3 and Comparative examples 1–3

Six types of film compositions were prepared at 60°C according to the mixing formulation in Table-1.

Table-1

Film composition / Quantity / Mixture component	Embodiment			Comparative Example		
	1	2	3	1'	2'	3'
	Parts by weight					
Dual-treated gelatin (200 bloom)	100	...	...	100	...	...
Acid-treated gelatin (150 bloom)	...	100	...	...	100	...
Alkali-treated gelatin (300 bloom)	...	...	100	...	...	100
Citric acid	1	1	1	...	...	...
D-sorbit	10	10	10	10	10	10
Purified water	Resi	Resi	Resi	Resi	Resi	Resi
Total quantity	370	370	370	370	370	370

Using the resultant film compositions 1–3 and 1'–3', soft capsule preparations 1–3 and 1'–3' were manufactured by the conventional method using a capsule-making machine (made by Morishita Jintan KK).

The general properties and preparation speed of the soft capsule preparations are shown in Table-2 and Table-3, respectively.

Table-2

Particle size of capsule	8 mm φ
Total weight of capsule	270 mg
Weight of content	230 mg
Weight of film	40 mg
Thickness of film	0.2 mm
Content	Wheat germ oil

Table-3

Soft capsule preparation / Manufacture speed	Embodiment			Comparative example		
	1	2	3	1'	2'	3'
Quantity per second	42*	38*	42*	42*	38*	42*

~~* Manufacture conditions~~

100g of the resultant soft capsule preparations were placed into a sealed container and stored at 40°C, after which disintegration time was measured according to the disintegration test method in the 10th edition of the Japanese Pharmacopoeia. Measurement results are shown in Table-4.

Table-4

Soft capsule / Storage prep. length (days)	Embodiment			Comparative Example		
	1	2	3	1'	2'	3'
0	Within 2 mins	Within 2 mins	Within 2 mins	Within 2 mins	Within 2 mins	Within 2 mins
7	Within 2 mins	Within 2 mins	Within 2.5 mins	Within 3 mins	Within 3 mins	Within 3.5 mins
14	Within 2.5 mins	Within 3 mins	Within 3.5 mins	Within 3.5 mins	Within 4.5 mins	Within 10 mins
21	Within 3.0 mins	Within 3.0 mins	Within 5.1 mins	Within 5 mins	Within 5.0 mins	20< mins[1]
28	Within 3.5 mins	Within 4.0 mins	Within 8.0 mins	Within 9 mins	Within 15 mins	...
35	Within 5 mins	Within 5 mins	Within 8.0 mins	20< mins[1]	20< mins[1]	...
42	Within 8 mins	Within 7 mins	20< mins[1]	...	...	...
49	Within 8 mins	Within 9 mins	...	...	...	...
56	Within 10 mins	Within 9 mins	...	...	...	...
63	Within 10 mins	Within 10 mins	...	...	...	...

1) Maximum value for disintegration test according to the Japanese Pharmacopoeia: 20 minutes